

REMARKS

In the Office Action dated July 19, 2010, it was stated that newly submitted claim 29 was directed to a distinct and independent invention from the invention originally claimed in the other pending claims. Therefore, claim 29 was withdrawn from consideration. Claims 3-6, 12, 13, 15-19 and 21-23 were rejected as being unpatentable over Houston et al. (U.S. Pat. Pub. 2002/0179166) (Houston), in view of Evans et al. (U.S. Pat. No. 5,709,713) (Evans), in view of Edwin et al. (U.S. Pat. No. 6,053,943) (Edwin). Claims 9 and 10 were rejected under 35 U.S.C. § 103 as being unpatentable over Houston in view of Evans and Edwin and further in view of Inderbitzen et al. (U.S. Pat. No. 5,484,411) (Inderbitzen). Claim 20 was rejected as being unpatentable over Houston in view of Evans and Edwin and in further view of Igaki et al. (U.S. Pat. No. 5,733,327) (Igaki). Claims 24 and 28 were rejected as being unpatentable over Houston in view of Evans and in further view of Nunez et al. (U.S. Pat. No. 6,596,023) (Nunez). Claims 24 and 28 were rejected over Houston in view of Evans and in further view of Cymbalisty (U.S. Pat. No. 6,896,007). For the reasons outlined in detail below, it is respectfully submitted that the pending claims are in condition for allowance over the art of record.

Examiner Interview

Examiners Tanner and Sonnett are thanked for the courtesy of providing an interview to applicant's attorney on 14 December 2010. Discussed during the interview were Houston, Evans, Edwin and Nunez. An agreement was reached that proposed amended claim 1 appears to overcome the combination of the prior art of record. Moreover, it was agreed that the Nunez reference failed to teach a helix and a swirl flow and, therefore, claim 24 overcomes the Nunez reference, and the three way combination of Houston, Evans and Nunez.

As discussed during the interview, applicant has amended pending independent claim 12 to recite that the helical center line of the flow lumen and of the helical portion have substantially equal pitches when the stent is expanded. This subject matter is supported by, e.g., Figures 1 and 2 of the instant specification, as well as page 6, lines 32-34. As discussed during the interview, claim 12 as so amended patentably defines over the asserted combination of Houston, Evans and Edwin.

Dependent claims 3-6, 13, 15-19 and 21-23 are also patentable over the asserted combination, as they merely further patentably describe the detailed subject matter of their parent claim or each other.

Moreover, dependent claims 9 and 10 are patentable over the combination of Houston, Evans, Edwin and Inderbitzen, as Inderbitzen does not provide those teachings which are clearly absent from the applied three-way combination.

Claim 20 is patentable over the applied four-way combination of Houston, Evans, Edwin and Igaki. Igaki does not provide those teachings which are clearly absent from the applied three-way combination.

Independent Claim 24 and Dependent Claim 28

These claims were rejected over the combination of Houston, Evans and Nunez, and also over the combination of Houston, Evans and Cymbalistry.

The Nunez reference was discussed during the interview. It was agreed that Nunez fails to teach a helix and a swirl flow.

As to Cymbalistry, it is noted that Cymbalistry pertains to non analogous art because it shows a hydro dynamic static mixing apparatus for separating oil sands and the like. The construction shown in Cymbalistry has nothing to do with a stent for insertion in a fluid conduit of a human or animal body as recited in claim 24. In fact, Cymbalistry teaches a structure which is grossly disproportionate with and in a totally different field from the structure of the references with which it is attempted to be combined. Therefore, the proposed combination is not tenable. In sum, independent claim 24 and dependent claim 28 patentably define over both of the asserted three-way combinations of references, Houston, Evans and Nunez on the one hand, and Houston, Evans and Cymbalistry on the other.

New Claims

Applicants submit herewith new independent claim 30 and dependent claims 31-33.

Claim 30 recites a stent for insertion into a fluid conduit of a human or animal body when the stent is in a collapsed condition and for expansion of the stent to an expanded condition. In the expanded condition, the stent causes the fluid conduit to

have a flow lumen having a center line which follows a substantially helical path. The stent comprises an outer wall for engagement with an associated fluid conduit, wherein the outer wall in the expanded condition of the stent follows a substantially helical path so as to promote a swirl flow effect within the associated conduit. A helical portion is integral with the outer wall of the stent. In the expanded condition of the stent, the helical portion extends longitudinally and circumferentially on the outer wall. Also, in the expanded condition of the stent, the helical portion resists extension more than does a remainder of the outer wall.

The subject matter recited in claim 30 is amply disclosed in the instant application. For example, reference may be had to Figures 1, 2, 4 and 6. In all of these, it is apparent that a helical band or stripe or portion is integral with the stent outer wall. In the expanded condition of the stent, the helical portion resists extension of the stent more than does a remainder of the outer wall of the stent. In use, in one embodiment, the stent is deployed at a target site and expanded by a balloon or by the elasticity or shape memory properties of the strands 4 in Figs. 1 and 2. The helical portion 6 acts to restrict the extension and, hence, the expanded stent adopts a helical configuration in which the center line of the stent follows a helical path. See the instant specification, page 18, lines 7-13. One effect of the helical portion 6 is to create a cross sectional shape approximating a circle with a segment removed in the region corresponding to the helical portion, as seen in Figure 3 (see the instant specification, page 17, lines 24-27). When deployed, the stent will seek to expand either via balloon expansion or shape memory properties. The expansion is resisted in the vicinity of the helical portion by it being less expansible. In effect, the helical portion provides a resistance to the expansion of the rest of the wall of the stent. This will enable the stent to assume the desired shape for promoting swirl flow in a fluid conduit supported by the stent (see the instant specification, page 8, lines 7-23).

The structure recited in claim 30 cannot be found in any of the cited references, in any combination. It is noted particularly that Edwin discloses a structural support 26 which is positioned on the outside of the graft 10. Rather than being integral with the graft, the structural support 26 is mechanically bonded to the graft member 12, as discussed in Edwin at column 8, lines 22-29.

In sum, pending claim 30 patentably defines over any of the prior art in any combination.

Dependent claim 31 recites that the outer wall comprises a plurality of strands. One embodiment of such an outer wall is amply illustrated in Figures 1 and 2.

Claim 32 recites that the helical portion comprises at least one strand. Two such strands 8 are shown in the embodiment of Figures 1 and 2.

Finally, claim 33 recites that wherein the at least one strand of the helical portion is woven in a mesh of the plurality of strands of the outer wall. Again, one embodiment of this is illustrated in Figures 1 and 2. Other embodiments are shown in, e.g., Figures 4 and 6.

Dependent claims 31-33 also patentably define over the prior art, as they merely further recite the detailed subject matter of their parent claim or each other.

In sum, it is respectfully submitted that all of the pending claims are now in condition for allowance over the art of record. Such allowance is earnestly solicited.

Respectfully submitted,

FAY SHARPE LLP

December 20, 2010

Date


Jay F. Moldovanyi
Reg. No. 29,678
1228 Euclid Ave 5th Flr
Cleveland, Ohio 44115
(216) 363-9000